



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

10D

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/125,814 08/26/98 DOHI M 051505

HM22/0717
SUGHRUE MION ZINN MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE N W
WASHINGTON DC 20037

EXAMINER

BERMAN, A

ART UNIT	PAPER NUMBER
----------	--------------

1619

DATE MAILED:

07/17/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/125,814

Applicant(s)

DOHI ET AL.

Examiner

Alysia Berman

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-32,34 and 36-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-32,34 and 36-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of the request for extension of time, amendment and declaration filed 05 May 2000. Claims 19, 20, 23, 38, 40, 41 and 45 have been amended. Claims 19-32, 34 and 36-45 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19-32, 34 and 36-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claim 19, several words are misspelled so it is unclear what Applicant intends to claim. The misspelled words are hydroxyothyl cellulose and hydroxysthyl cellulose at line 7 and chisosan at line 12. Correction is required.

5. Regarding claims 24 and 25, the term "on/in" renders the claims indefinite. It is unclear how the drug can be dispersed on and in the bases. The addition of a drug dissolved in water to a water-absorbing material would result in the solubilized drug being absorbed into the water-absorbing material.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The instant application is drawn to a powdery composition comprising
- A. a drug,
 - B. about 5-40 wt % of one or more water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose and sodium carboxymethyl cellulose based on the total of both base materials, and
 - C. one or more water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α -cellulose, cross-linked sodium carboxymethyl cellulose, cross-linked starch, chitin and chitosan,

wherein the drug is unevenly dispersed more on or in the water-absorbing and water-insoluble base material (B) than on or in the water-absorbing and gel-forming base material (C).

8. Claims 19-26, 28-32, 34 and 36-45 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US 4,613,500 (Suzuki et al. '500).

This rejection is maintained for reasons of record. As stated in paper no. 5, US '500 discloses a powdery composition comprising a polypeptide (col. 2, line 57 to col. 3, line 25) that is absorbed onto or into a water-absorbing and water-insoluble base (col. 4, lines 21-41 and col. 5, lines 53-65). This composition may be combined with a water-absorbing and water-soluble (gel-forming) base (col. 5, lines 10-25).

A product obtained by a particular process is not considered patentable over the prior art product absent evidence of superior and unexpected results. See *In re Masosi*, 710 F.2d, 218

USPQ 289 and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964. Further, none of the claims require that the product be made by the processes disclosed.

Response to Arguments

9. Applicant's arguments filed 05 May 2000 have been fully considered but they are not persuasive.

10. Applicant argues that US '500 does not teach the drug unevenly dispersed on or in the water-absorbing and water-insoluble base material. However, US '500 does teach that the drug is dispersed on or in the water-absorbing and water-insoluble base at column 5, lines 53-65.

Although US '500 teaches that a water-absorbing and water-soluble (gel-forming) base may be added, it is silent as to whether or not the drug is dispersed on or in this base. Therefore, it is the examiner's opinion that the composition of US '500 obtains uneven dispersion of the drug as instantly claimed.

The declaration and graph have been considered. However, the graph does not clearly show what is being measured and graphed in order to determine unexpected and superior results. Applicant has not presented any data to show that a different product is obtained by Applicants' process than by the process of US '500. Further, none of the claims require any of the processes disclosed in the instant application.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 19-32, 34 and 36-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,613,500 as applied to claim 19 above and further in view of US 5,262,871 (Makino et al. '871).

This rejection is maintained for reasons of record. US '500 discloses all of the limitations of the claims as stated earlier. US '500 does not teach the use of non-peptide/non-proteinaceous drug. US '871 discloses non-peptide/non-proteinaceous drugs (col. 7, line 60 to col. 8, line 26) for use in powdery nasal compositions (col. 4, lines 11-13). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a non-peptide/non-proteinaceous drug as taught in US '871 for a peptide-proteinaceous drug in the composition of US '500 with the reasonable expectation of producing a powdery nasal composition. The motivation to do so stems logically from the art-recognized desire for a medicament that is efficiently absorbed through the nasal mucosa.

Response to Arguments

14. Applicant's arguments filed 05 May 2000 have been fully considered but they are not persuasive.

Art Unit: 1619

15. Applicant argues that US '871 does not supply the deficiencies of US '500. US '871 is used merely to show that it is known in the art to use non-peptide/non-proteinaceous drugs in powdery nasal compositions and that it would, therefore, have been obvious to substitute a non-peptide/non-proteinaceous drug for a peptide/proteinaceous drug as instantly claimed.

Presently no claim is allowed.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703/308-4638. The examiner can normally be reached on 8:00-4:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703/308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703/305-3704 for regular communications and 703/305-3704 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.


Alysia Berman
Patent Examiner
July 13, 2000


DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600